Can Denosumab Achieve Superiority For The Prevention Of SREs In Cancer?

Description: There are many large clinical trials currently being conducted with denosumab. It is being tested in osteoporosis, treatment induced bone loss, prevention of metastases in cancer, delay of skeletal related events in cancer, rheumatoid arthritis as well as other diseases. Upon completion of these trials, denosumab will be one of the most tested drugs and, if trials are successful, one of the most widely used.

Our current work focuses on the 3 phase III trials involving skeletal related events (SREs) in cancer. Denosumab is being compared to Zometa in its ability to delay/prevent SREs in breast cancer, prostate cancer, multiple myeloma and other advanced cancers. The patient population targeted for such treatment is large, and treatment can be administered for several years, making these trials of high financial impact to Amgen. Zometa is currently the standard of care for treating cancer patients with bone metastasis. It is an effective treatment that is well established. The primary endpoint of the SRE trials are non-inferiority of denosumab to Zometa, and superiority is the secondary endpoint.

There is not an abundance of clinical trial data to study to gauge the ability of denosumab to prevent SREs. No previous trials were undertaken with the primary endpoint of preventing/delaying SREs. There are two phase II studies and two phase III studies that report some data with regards to denosumab's effect on SREs. These trials provide some direction, but have complications with regards to dosing, duration of study, and types of drugs used. We provide careful analysis of these studies in this report.

Because of the limited conclusions we were able to derive from trials that report SRE data, we broadened our search for data and included analyses of trials in osteoporosis, treatment induced bone loss and biomarker reduction to further assess the ability of denosumab to have a positive outcome. Although data in these trials is not directly comparable to data in the SRE trials, denosumab can be compared to Zometa within the same disease area to compare the efficacy of the two drugs.

After careful analysis of over 20 trials, and discussions with several physicians, we believe we have a comprehensive understanding of how the efficacy and safety of denosumab compares to Zometa. We have paid careful attention to two phase II studies in cancer which have provided a foundation for opinions of the superiority of denosumab. There are important aspects of these trials that have not been publicized and need to be considered before concluding that superiority can be achieved. In addition, we have found two subpopulations for which denosumab may outperform Zometa. We also have insight into the statistics and powering of the 3 SRE trials and have run 10,000 iteration simulations of each to produce probabilities of outcomes. Our thorough assessment of the strengths and weaknesses of denosumab versus Zometa, and our in depth discussions with physicians, provide a comprehensive and well-informed conclusion regarding the likelihood of success of denosumab for the delay/prevention of SREs.

We have also examined the market impact denosumab will have if the SRE trials are successful. We have captured physician opinions of how usage of Zometa and Denosumab may change, what safety issues have been observed with both drugs, and what may persuade physicians to use one drug over the other given the choice of both.

This report investigates the 3 phase III trials involving skeletal related events (SREs) in cancer. Denosumab (Amgen) is being compared to Zometa (Novartis) in its ability to delay/prevent SREs in breast cancer, prostate cancer, multiple myeloma and other advanced cancers. It poses a large threat to the existing Zometa business. The main question is whether Denosumab will show non-inferiority or superiority to Zometa in these clinical trials, and what it will mean for the bone cancer market.

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